

REMARKS

Claims 1-3, 8-10, 18-20, 27 and 28 are pending, claims 4-7, 11-17, and 21-26 having been withdrawn by the Examiner pursuant to 37 C.F.R. 1.142 § (b), and cancelled by applicants' Amendment A of 01 February 2002.

Applicants thank the Examiner for considering applicants' Amendment B of 22 November 2002, including the Affidavits of Dr. Edward Neuwelt and Dr. Gail M. Clinton, and for withdrawing, in view thereof, the claim rejections under 35 U.S.C. § 112 ¶¶ 1 and 2 (*see* Office Action of 11 March 2003, at pages 2-3, paragraphs 4-6).

Applicants also thank the Examiner for allowance of amended claims 1-3 and 8-10 (*Id.*).

Applicants further thank the Examiner for indicating that amended claims 19 and 20 (currently not allowable in view of the present rejection of independent claim 18) would be allowable if rewritten in independent form, although in the case of claim 20, the Examiner's indication of conditional allowability is inconsistent with the Examiner's claim 18 rejection. Applicants, nonetheless, do not herein further amend claims 19 and 20, but rather traverse the Examiner's rejection of claim 18, as described below.

Applicants acknowledge the Examiner's New Grounds of Rejection of claims 27 and 28, in view of the alleged similarity in claim scope to claims 3 and 10, respectively (*Id.* at page 3, para 7). Applicants have accordingly further amended claims 3 and 10 to clarify the subject matter and remove any ambiguity regarding similarity of scope.

Applicants also acknowledge the Examiner's New Grounds of Rejection of claim 18, under 35 U.S.C. 102(e), in view of *Hudziak*. Applicants respectfully traverse this claim rejection as described herein below.

Finally, new *dependent* claims 29 and 30, depending from claim 18 and fully supported by the originally filed specification, have been added.

No new matter has been added.

FORMALITIES

Applicants, to clarify the subject matter and conform with the previously amended claims, have further amended the specification as indicated above to clarify the units of binding affinity as is well known in the relevant art and as is supported by the originally filed specification. Support for these amendments is described in detail in applicants' Amendment A of 01 February 2002, at page 8. No new matter has been added.

Applicants have non-substantively amended allowed claim 8 to recite "is" in place of "are," to correct grammar. No new matter has been added.

Applicants have also non-substantively amended allowed claim 9 to replace the inadvertently omitted word "sites" in the context of "N-linked glycosylation sites." Support for this amendment is found throughout the originally filed specification including the claims thereof. No new matter has been added.

Applicants, as indicated previously, have prepared final formal drawings (Figures 1-7, attached hereto) in response to the Draftsperson's comments. No new matter has been added.

New Grounds of Rejection

Claims 27 and 28 were objected to by the Examiner, "because they appear to be of exactly the same scope as claims 3 and 10," respectively (Office Action of 11 March at page 3, para 7).

Applicants have amended dependent claims 3 and 10, which now recite "comprises SEQ ID NO:1" in place of "consists of SEQ ID NO:1." By contrast, claims 27 and 28 recite "consisting of the amino acid sequence of SEQ ID NO:1," and are thus of different scope than the currently amended claims 3 and 10, respectively. No new matter has been added.

Applicants, therefore, respectfully request withdrawal of the Examiner's objection with respect to claims 27 and 28.

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Rejections under 35 U.S.C. § 102(e)

The Examiner also rejected claim 18 under 35 U.S.C. § 102(e) as being anticipated by **Hudziak** (U.S. Patent 6,399,063; issued 04 June 2002; effective filing date of 25 January 1988) (Office Action of 29 January 2003, at page 10, para 12).

Specifically, the Examiner asserts that “Hudziak discloses pharmaceutical compositions comprising an antibody to HER-2 and a second agent, such as a cytokine (TNF-alpha, TNF-beta, IL-2, Interferon-gamma; see col. 7, lines 3-61; claims 8-13),” thereby allegedly disclosing the instant claimed pharmaceutical compositions.

Applicants respectfully *traverse* this rejection, because the instant Markush group of agents is neither anticipated by, nor obvious in view of any alleged *genus* of Hudziak. Specifically, applicants’ invention is the first and only disclosure of naturally occurring p185HER-2 binding proteins and antagonists. The instant binding proteins, and their binding specificity are unique, and distinct from any the “second agents” of Hudziak. Thus, the instant species/embodiments are novel, and are neither anticipated by, nor obvious in view of any alleged “second agent” genus of Hudziak, the species of which do not bind to p185HER-2 and do not include fusion proteins; that is, the instant agents are not species of any alleged Hudziak genus. This is particularly clear in view of applicants’ amended recitation of *contiguous* amino acid residues in the instant claims, including amended claim 18.

Therefore, even if the instant embodiments were considered as species of an alleged encompassing Hudziak “second agent” genus (which they are not), the present embodiments are novel and non-obvious in view of said genus, and would therefore be patentably distinct even in view of said prior disclosed genus. Here, as in many instances in the chemical arts, the alleged genus does not anticipate the present species (assuming they are species, which they are not).

Furthermore, applicants respectfully contend that the fact that such a Hudziak “second agent” genus claims might *dominate* (for infringement purposes) any aspect of the present claimed subject matter is irrelevant in the sense of the present § 102(e) rejection, and applicants need not take any position as to any such potential *dominance*. In fact, it is the applicants’ position that the

instant claimed embodiments do not comprise any species of Hudziak, and are, therefore, would not be dominated thereby in infringement sense.

Applicants, therefore, respectfully request withdrawal of the Examiner's § 102(e) rejection with respect to previously amended claim 18.

New Claims

Applicant's have added new *dependent* claims 29 and 30, drawn to pharmaceutical compositions comprising the amino acid sequence of SEQ ID NO:2 or a fragment of SEQ ID NO:2 of about 80 to 419 contiguous residues in length (claim 29), or to the combination of same and the monoclonal antibody that binds to the extracellular domain (ECD) of HER-2 (claim 30).

These *dependent* claims, in essence, are the SEQ ID NO:2 versions/analogues of dependent claims 19 and 20 (that recite SEQ ID NO:1), and are, like claims 19 and 20, fully supported by the specification and by independent claim 18. No new matter has been added.

CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully request allowance of claim 1 (Previously amended), 2 (Previously amended), 3 (Currently amended), 8 (Currently amended), 9 (Currently amended), 10 (Currently amended), 18-20 (all Previously amended), 27 and 28 (both Previously added) and claims 29 and 30 (both New), provided herein above.

The Examiner is encouraged to phone applicants' attorney, Barry L. Davison, to resolve any outstanding issues and expedite allowance of this application.

No new matter has been added.

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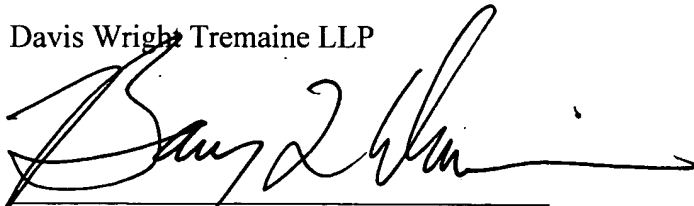
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Entry of the Amendment is respectfully requested.

Respectfully submitted,

Davis Wright Tremaine LLP

A handwritten signature in black ink, appearing to read 'Barry L. Davison', written over a horizontal line.

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